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(54) EXPANDABLE STENT

AUFWEITBARER STENT

PROTHESE ENDOVASCULAIRE EXTENSIBLE

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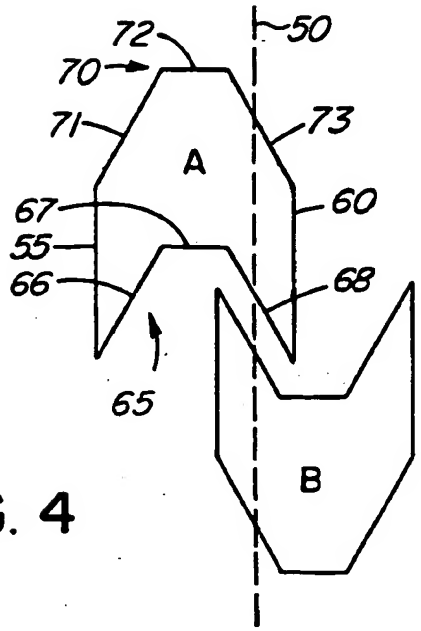

FIG. 4

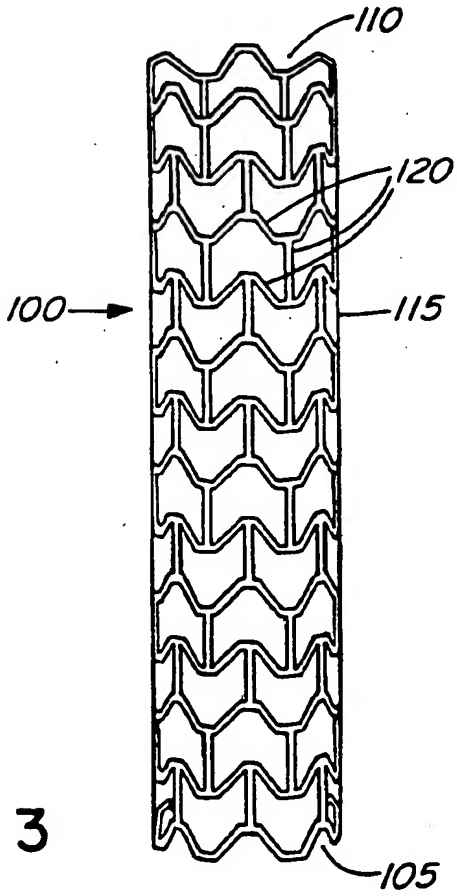

FIG. 3

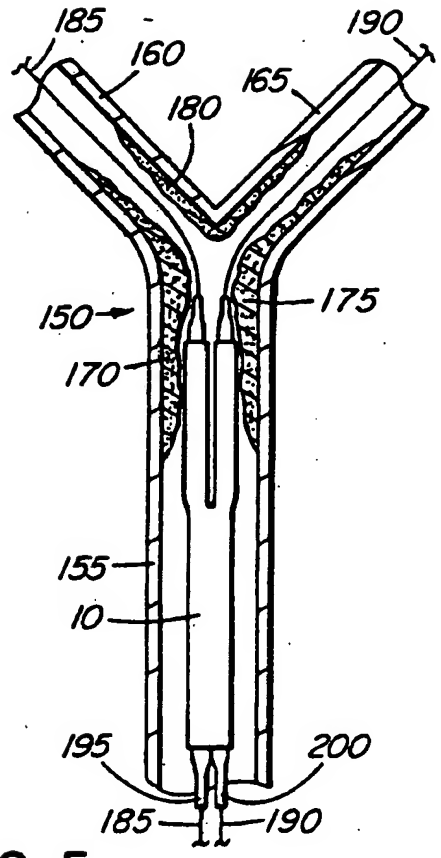

FIG. 5

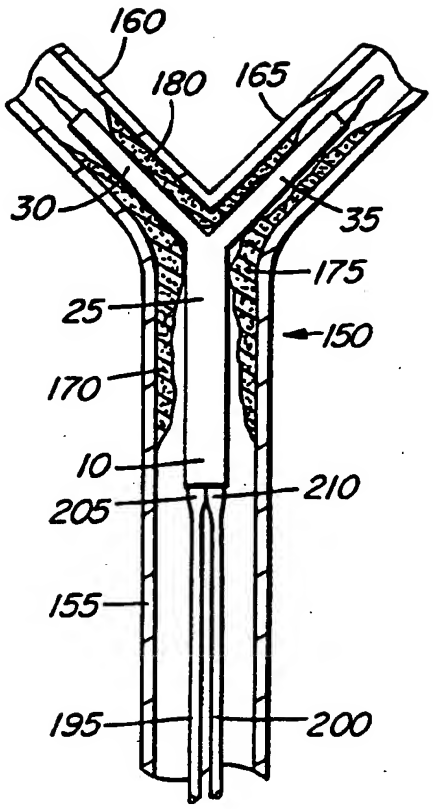

FIG. 6

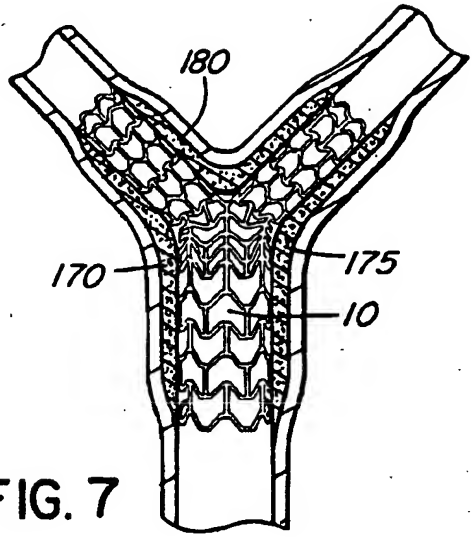

FIG. 7

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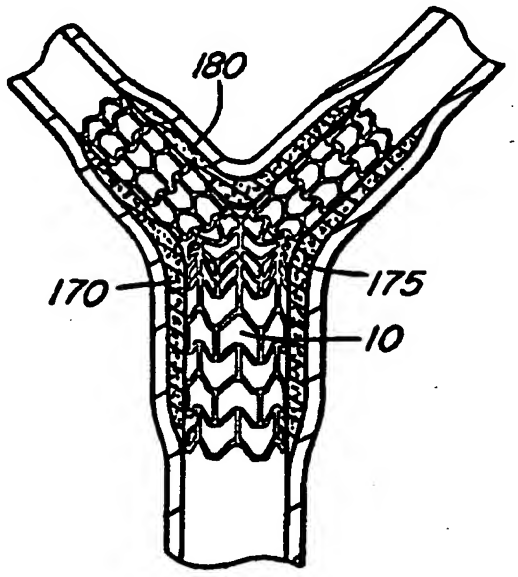
(54) Title: EXPANDABLE BIFURCATED STENT AND METHOD FOR DELIVERY OF SAME

(57) Abstract

An expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality intersecting members arranged to define a first repeating pattern which is a polygon having a pair of side walls substantially parallel to the longitudinal axis, a first concave-shaped wall and a second convex-shaped wall connecting the side walls, the first wall and the second wall being equidistant along an axis which is parallel to the longitudinal axis, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the interior of the stent. A particularly preferred form of the stent is an expandable bifurcated stent comprising a proximal end and a distal end in communication with one another, the proximal end comprising a primary passageway and the distal end comprising a pair of secondary passageways, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent. A method of delivering the bifurcated stent to a target body passageway is also provided.



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EXPANDABLE BIFURCATED STENT AND METHOD FOR DELIVERY OF SAME

TECHNICAL FIELD

The present invention relates to an expandable bifurcated stent and to a method for delivery of same.

BACKGROUND ART

Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expansible prosthesis". As used throughout this specification the term "stent" is intended to have a broad meaning and encompasses any expandable prosthetic device for implantation in a body passageway (e.g. a lumen or artery).

In the past six to eight years, the use of stents has attracted an increasing amount of attention due the potential of these devices to be used, in certain cases, as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct (e.g. natural or iatrogenic) within the human body and can include a member selected from the group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.

Initial stents were self-expanding, spring-like devices which were inserted in the body passageway in a contracted state. When released, the stent would automatically expand and increase to a final diameter dependent on the size of the stent and the elasticity of the body passageway. Such stents were known in the art as the Wallstent™.

The self-expanding stents were found by some investigators to be deficient since, when deployed, they could place undue, permanent

stress on the walls of the body passageway. This lead to the development of various stents which were controllably expandable at the target body passageway so that only sufficient force to maintain the patency of the body passageway was applied in expanding the stent.

Generally, in these later systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once the stent has been properly located (the target area of the body passageway can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is expanded thereby expanding the stent so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to maintain the patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and subsequently removed. Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

A stent which has gained some notoriety in the art is known as the Palmaz-Schatz™ Balloon Expandable Stent (hereinafter referred to as "the Palmaz-Schatz stent"). This stent is discussed in a number of patents including United States patents 4,733,665, 4,739,762, 5,102,417 and 5,316,023, the contents of each of which are hereby incorporated by reference.

Another stent which has gained some notoriety in the art is known as Gianturco-Roubin Flex-Stent™ (hereinafter referred to as "the Gianturco-Roubin stent"). This stent is discussed in a number of patents including United States patents 4,800,882, 4,907,336 and 5,041,126, the contents of each of which are hereby incorporated by reference.

Other types of stents are disclosed in the following patents:

United States patent 5,035,706 (Gianturco et al.),

United States patent 5,037,392 (Hillstead),
United States patent 5,147,385 (Beck et al.),
United States patent 5,282,824 (Gianturco),
Canadian patent 1,239,755 (Wallsten), and
Canadian patent 1,245,527 (Gianturco et al.),

the contents of each of which are hereby incorporated by reference.

All of the stents described in the above-identified patents share the common design of being mono-tubular and thus, are best suited to be delivered and implanted in-line in the body passageway. These known stents are inappropriate for use in a bifurcated body passageway (e.g. a body passageway comprising a parent passageway that splits into a pair of passageways). Further, these stents are inappropriate for use in a body passageway having side branches since: (i) accurate placement of the stent substantially increases the risk to the patient, (ii) the risk of passageway closure in the side branches is increased, and (iii) the side branches will be substantially inaccessible.

Indeed the Physician Guide published in support of the Palmaz-Schatz stent states on page 32 (the contents of which are hereby incorporated by reference):

> " ... no attempt should be made following placement of a PALMAZ-SCHATZ stent to access the side branch with a guide wire or a balloon, as such attempts may result in additional damage to the target vessel or the stent. Attempts to treat obstructed side branches within stented segments can result in balloon entrapment, necessitating emergency bypass surgery."

Thus, when installed, the Palmaz-Schatz stent admittedly shields side branches emanating from the target area of the body passageway effectively permanently. This can be problematic since the only way to treat blockage or other problems associated with the side branches is to perform the type of surgery which installation of the stent was intended to avoid.

This contraindication for conventional mono-tubular stents is corroborated by a number of investigators. See, for example, the following:

1. *Interventional Cardiovascular Medicine: Principles and Practice* (1994); Publisher: Churchill Livingstone Inc.; pages 221-223 (Ohman et al.), 487-488 (Labinaz et al.), 667-668 (Bashore et al.) and 897 (Bailey et al.), including references cited therein;

2. Gianturco-Roubin Flex-Stent™ Coronary Stent: Physician's Guide; page 2, Paragraph 3 under WARNINGS;

3. *Circulation*, Vol. 83, No. 1, January 1991 (Schatz et al.); entitled "Clinical Experience With the Palmaz-Schatz Coronary Stent"; pages 148-161 at page 149; and

4. *American Heart Journal*, Vol. 127, No. 2, February 1994 (Eeckhout et al.); entitled "Complications and follow-up after intracoronary

stenting: Critical analysis of a 6-year single-center experience"; pages 262-272 at page 263,

the contents of each of which are hereby incorporated by reference.

Further, some investigators have attempted to install individual stents in each branch of the bifurcated body passageway. However, this approach is fraught with at least two significant problems. First, implantation of three individual stents, together with the expansive forces generated upon implantation results in subjecting the central walls of the bifurcated body passageway to undue stress which may lead to post-procedural complications. Second, since the central walls of the bifurcated body passageway are not supported by the individual stents, this area of the passageway is left substantially unprotected and susceptible to blockage.

One particular problem area with bifurcated body passageways is the occurrence of bifurcation lesions within the coronary circulation. Generally, these legions may be classified as follows:

Type	Characteristic
A	Prebranch stenosis not involving the ostium of the side branch;
B	Postbranch stenosis of the parent vessel not involving the origin of the side branch;
C	Stenosis encompassing the side branch but not involving the ostium;

Type	Characteristic
D	Stenosis involving the parent vessel and ostium of the side branch;
E	Stenosis involving the ostium of the side branch only; and
F	Stenosis discretely involving the parent vessel and ostium of the side branch.

See *Atlas of Interventional Cardiology* (Popma et al.), 1994, pages 77-79, the contents of which are hereby incorporated by reference. The presence of bifurcation lesions is predictive of increased procedural complications including acute vessel closure.

Detailed classification of other bifurcated body passageways is relatively undeveloped given the lack of non-surgical treatment approaches.

Indeed, to the knowledge of the Applicant's, heretofore, a proven expandable bifurcated stent has been unavailable.

It would be desirable to have an expandable bifurcated stent since this would be useful in treating aneurysms, blockages and other ailments. It would also be desirable if such a stent was relatively easy to install.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a novel expandable bifurcated stent which obviates or mitigates at least one of the above-mentioned disadvantages of the prior art.

Descripti n

TECHNICAL FIELD

The present invention relates to an expandable stent as specified in the preamble of Claim 1. Such a stent is e.g. known from EP-A-0 566 807.

BACKGROUND ART

Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expansible prosthesis". As used throughout this specification the term "stent" is intended to have a broad meaning and encompasses any expandable prosthetic device for implantation in a body passageway (e.g. a lumen or artery).

In the past six to eight years, the use of stents has attracted an increasing amount of attention due the potential of these devices to be used, in certain cases, as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct (e.g. natural or iatrogenic) within the human body and can include a member selected from the group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.

Initial stents were self-expanding, spring-like devices which were inserted in the body passageway in a contracted state. When released, the stent would automatically expand and increase to a final diameter dependent on the size of the stent and the elasticity of the body passageway. Such stents were known in the art as the Wallstent™.

The self-expanding stents were found by some investigators to be deficient since, when deployed, they could place undue, permanent stress on the walls of the body passageway. This lead to the development of various stents which were controllably expandable at the target body passageway so that only sufficient force to maintain the patency of the body passageway was applied in expanding the stent.

Generally, in these later systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once the stent has been properly located (the target area of the body passageway can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is expanded thereby expanding the stent so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to maintain the patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and subsequently removed. Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

A stent which has gained some notoriety in the art is known as the Palmaz-Schatz™ Balloon Expandable Stent (hereinafter referred to as "the Palmaz-Schatz stent"). This stent is discussed in a number of patents including United States patents 4,733,665, 4,739,762, 5,102,417 and 5,316,023.

Another stent which has gained some notoriety in the art is known as Gianturco-Roubin Flex-Stent™ (hereinafter referred to as "the Gianturco-Roubin stent"). This stent is discussed in a number of patents including United States patents 4,800,882, 4,907,336 and 5,041,126.

Other types of stents are disclosed in the following patents:

United States patent 5,035,706 (Gianturco et al.),
United States patent 5,037,392 (Hillstead),
United States patent 5,147,385 (Beck et al.),
United States patent 5,282,824 (Gianturco),
Canadian patent 1,239,755 (Wallsten), and
Canadian patent 1,245,527 (Gianturco et al.).

Published European patent application 0,566,807A teaches a stent having a porous surface including a repeating pattern made of up a polygon having three parallel side walls (and parallel to the longitudinal axis of the stent) connected by a concave-shaped wall and a convex-shaped wall. Each of the concave-shaped wall and the convex-shaped wall of the polygon in the subject stent are characterised by a pointed apex. A stent having the provision of such a repeating pattern is fraught with the following deficiencies: the stent will not open properly upon application of an expansive force; upon expansion, the stent is susceptible to improper lifting at the intersection point (i.e., in a two-dimensional representation of the stent design, such lifting would be in a third dimension); the stent is relatively inflexible; the stent will not expand in a symmetrical fashion; and the stent can not be opened to a consistent degree using a consistent pressure.

Further, all of the stents described in the above-identified patents share the common design of being mono-tubular

It is another object of the present invention to provide a novel method for implanting an expandable bifurcated stent.

Accordingly, in one of its aspects, the present invention provides an expandable bifurcated stent comprising a proximal end and a distal end in communication with one another, the proximal end comprising a primary passageway and the distal end comprising a pair of secondary passageways, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force exerted on the stent.

In another of its aspects, the present invention provides an expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality intersecting members arranged to define a first repeating pattern which is a polygon having a pair of side walls substantially parallel to the longitudinal axis, a first concave-shaped wall and a second convex-shaped wall connecting the side walls, the first wall and the second wall being equidistant along an axis which is parallel to the longitudinal axis, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force exerted on the stent.

In yet another of its aspects, the present invention provides a method for delivery to a target body passageway of an expandable bifurcated stent comprising a proximal end and a distal end in communication with one another, the proximal end comprising a primary passageway and the distal end comprising a pair of secondary passageways, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force exerted on the stent, the method comprising the steps of:

disposing the stent in the first, contracted position on a catheter;

inserting the stent and catheter within the target body passageway by catheterizati n of the target body passageway;

exerting a radially outward expansive force on the stent such that the stent assumes the second, expanded position and is urged against the target body passageway.

Thus, an aspect of the present invention relates to the provision of an expandable bifurcated stent. To the knowledge of the Applicant's, an expandable bifurcated stent has heretofore been unknown. As used throughout this specification, the term "bifurcated stent" is intended to have a broad meaning and encompasses any stent having a primary passageway to which is connected at least two secondary passageways. Thus, trifurcated stents are encompassed herein. Further, one of the secondary passageways can be a continuation of the primary passageway with the result that the other secondary passageway is essentially a side branch to the primary passageway.

The Applicant's have also discovered that the use of a specific repeating pattern in a porous stent is particularly advantageous. Generally, the repeating pattern is a polygon having a pair of side walls substantially parallel to the longitudinal axis of the stent passageway in question, a first concave-shaped wall and a second convex-shaped wall connecting the side walls, the first wall and the second wall being equidistant along an axis which is parallel to the longitudinal axis of the stent passageway in question. As used throughout this specification, the terms "concave-shaped" and "convex-shaped" are intended to have a broad meaning and a shape having apex. Thus, the apex can be the top of a smooth curve. Alternatively, the apex can be a point or top of a segmented line. The important point is that the apex of the concave-shaped wall is directed into the polygon whereas the apex of the convex-shaped wall is directed away from the polygon.

This repeating pattern is useful in both the novel bifurcated stent described herein and conventional mono-tubular stents. The advantages associated with the use of such a repeating pattern include the following:

1. The stent is controllably expandable;
2. The stent is flexible and thus, can be deliver via and/or implanted in curved body passageways; and
3. Access to side branches is maintained, unlike the Palmaz-Schatz stent described hereinabove.

The stent of the present invention (bifurcated or mono-tubular) can further comprise coating material therein. The coating material can be one or more of a biologically inert material (i.e. to reduce the thrombogenicity of the stent), a medicinal composition which leaches in the wall of the body passageway after implantation (e.g. to provide anticoagulant action and the like).

BRIEF DESCRIPTION OF THE DRAWING

Embodiments of the present invention will be described with reference to the accompanying drawings wherein like numerals designate like parts and in which:

Figure 1 illustrates a perspective view of a bifurcated stent in a first, contracted position;

Figure 2 illustrates an enlarged perspective view of the bifurcated stent of Figure 1 in a second, expanded position;

Figure 3 illustrates a perspective view of a mono-tubular stent in a second, expanded position;

Figure 4 illustrates an expanded two-dimensi nal representation of the repeating patterns present in the stents illustrated in Figure 1-3;

Figure 5 illustrates a cross-section of a bifurcated body passageway into which the bifurcated stent of Figure 1 is being delivered;

Figure 6 illustrates a cross-section of a bifurcated body passageway in which the bifurcated stent of Figure 1 is positioned in a first, contracted position; and

Figure 7 illustrates a cross-section of a bifurcated body passageway in which the bifurcated stent of Figure 1 positioned in a second, expanded position.

BEST MODE FOR CARRYING OUT THE INVENTION

With reference to Figure 1, there is illustrated a stent 10. Stent 10 comprises a proximal end 15 and a distal end 20. Proximal end 15 comprises a primary passageway 25. Distal end 20 comprises a pair of secondary passageways 30,35. Secondary passageways 30,35 are connected to primary passageway 25 at an intersection point 40. As will be appreciated by those of skill in the art, the length of primary passageway 25 and secondary passageways 30,35 is particularly restricted and is select to optimize both deliverability of the stent (shorten) and vessel coverage (lengthen).

With reference to Figure 2, there is illustrated an enlarged perspective view of the bifurcated stent illustrated in Figure 1 in a second, expanded position. As illustrated, secondary passageways 30,35 are split apart more than they are when the bifurcated stent is in the first, contracted position (Figure 1).

As illustrated, primary passageway 25 and secondary passageways 30,35 are porous. The porosity of these passageways is defined by a plurality of intersecting members 45. Intersecting members 45 define a first repeating pattern designated A and a second repeating pattern designated B in Figure 2. The nature of first repeating pattern A and

second repeating pattern B will be discussed in more detail hereinbelow with reference to Figure 4.

With reference to Figure 3, there is illustrated a perspective view of a mono-tubular stent 100. Stent 100 comprises a proximal end 105 and a distal end 110. Disposed between proximal end 105 and distal end 110 is a tubular wall 115. Tubular wall 115 is porous. The porosity of tubular wall 115 is defined by a plurality of intersecting members 120 which define a first repeating pattern A and second repeating pattern B.

With reference to Figure 4, there is illustrated an enlarged two-dimensional representation of first repeating pattern A and second repeating pattern B. These repeating patterns are illustrated with respect to a longitudinal axis 50 which is representative of the longitudinal axis which would be present in each of primary passageway 25, secondary passageways 30,35 and tubular wall 115 discussed above with reference to Figures 1, 2 and 3. As illustrated, repeating pattern A is a polygon comprising a pair of side walls 55,60. Side walls 55,60 are substantially parallel to longitudinal axis 50. Side walls 55,60 are connected by a concave-shaped wall 65 and a convex-shaped wall 70.

As illustrated, concave-shaped wall 65 is made up of a trio of segments 66,67,68. In the illustrated embodiment, segment 67 is the apex of concave-shaped wall 65. Convex-shaped wall 70 is made up of a trio of segments 71,72,73. In the illustrated embodiment, segment 72 is the apex of convex-shaped wall 70.

It will be appreciated by those of skill in the art that the provision of first repeating pattern A, as illustrated, necessarily defines and provides for second repeating pattern B. It will also be appreciated by those of skill in the art that second repeating pattern B is a mirror image of first repeating pattern A taken al ng an axis (not shown) substantially normal to longitude general axis 50.

It will be further appreciated by those of skill in the art that the shape of concave-shaped wall 65 and/or convex-shaped wall 70 can be modified without departing from the function and performance of the stent. For example, the trio of segments can be replaced by a suitably curved or arcuate wall. Alternatively, more than three segments can be used to define concave-shaped wall 65 and/or convex-shaped wall 70. Other modifications will be apparent to those of skill in the art.

It will be further appreciated by those of skill in the art that various walls of first repeating pattern A and second repeating pattern B may be omitted (and even desired) at selected points along the body of the stent without departing from the spirit and scope of the invention. For example, it is possible to omit one or both of side walls 55,60 at selected points along the body of the stent with a view to improving the longitudinal flexibility of the stent. Further, it is possible to omit one or more of segments 71,72,73 at selected points along the body of the stent with a view to improving the lateral flexibility of the stent.

With further reference to Figure 2, it will be evident to those of skill in the art that intersection point 40 is an annular arrangement of second repeating pattern B which has been modified. Specifically, the modification is in two areas. First, a reinforcing bar 75 has been disposed between side walls 55,60 to connect segments 67 and 72. Second, a reinforcing segment 80 is provided midway between and has a similar shape to concave-shaped wall 65 and convex-shaped wall 70. These two areas of modification serve to reinforce intersection point 40. This facilitates alleviation of stresses under which this area of stent 10 is placed when it is expanded. It will of course be appreciated by those of skill in the art that modifications can be made to the design of intersection point 40 without departing from the spirit and scope of the inventi n. For example, the flexibility of stent 10 at intersection point

40 can be modified by judicious addition or omission of further reinforcing bars 75 and/or reinforcing segments 80.

With reference to Figures 5 and 6, there is illustrated a bifurcated body passageway 150 comprised of a proximal passageway 155 and a pair of distal passageways 160,165. As illustrated, bifurcated body passageway 150 comprises a Type "D" Bifurcation lesion having characteristic blockages 170,175,180.

Stent 10 is delivered to bifurcated body passageway 150 in the following manner. Initially, a pair of guidewires 185,190 are inserted into proximal passageway 155 such that guidewire 185 enters distal passageway 160 and guidewire 190 enters distal passageway 165. The manner by which the guidewires are inserted is conventional and within the purview of a person skilled in the art.

As illustrated, stent 10 is positioned in association with a pair of catheters 195,200 (for clarity, the interior of stent 10 is not shown). Catheter 195 has associated with it a balloon 205. Catheter 200 has associated with it a balloon 210. Balloons 205,210 substantially fill primary passageway 25 of stent 10. Balloon 205 substantially fills secondary passageway 30 of stent 10. Balloon 210 substantially fills secondary passageway 35 of stent 10.

The stent/catheter/balloon combination is delivered through proximal passageway 155 with the aid of guidewires 185,190. As the stent/catheter/balloon combination approaches distal passageways 160,165, predisposition of guidewires 185,190 serves to separate secondary passageways 30,35 to be disposed in distal passageways 160,165, respectively. Thus, as illustrated in Figure 6, stent 10 is positioned in place.

Once stent 10 is in position, balloons 205,210 are expanded resulting in implantation of stent 10 in the corresponding interior surfaces of proximal passageway 155 and distal passageways 160,165.

Upon implantation of stent 10, balloons 205,210 are collapsed. Thereafter, catheters 195,200 and guidewires 185,190 have been removed leaving the implanted stent 10 shown in Figure 7. As illustrated in Figure 7, blockages 170,175,180 are bulged radially outwardly in combination with the appropriate portions of proximal passageway 155 and distal passageways 160,165 resulting in a reduction in the overall blockage in bifurcated body passage 150.

It will be apparent to those of skill in the art that implantation of stent 10 can be accomplished by various other means. For example, it is contemplated that it is possible to substitute the pair of catheter/balloon combinations illustrated in Figures 5 and 6 with a single, bifurcated catheter/balloon design which mimics the design of the stent. Thus, in this modification, the balloon and guidewire would be design to mimic the bifuracted design of the stent. As further alternative, it is contemplated that the stent can be made of a suitable material which will expand when bifurcated body passageway 150 is flushed with a liquid having an elevated temperature (e.g. 150°F-160°F). Further, stent 10 can be designed to expand upon the application of mechanical forces other than those applied by a balloon/catheter. Still further, stent 10 can be designed self-expanding to be implanted as described above. In this embodiment, the radially outward force exerted on the stent would be generated within the stent itself.

With regard to mono-tubular stent 100 depicted in Figure 3, this stent can be implanted using a system similar to the one described above with reference to bifurcated stent 10 (Figures 5-7). In this instance, of course, a single guidewire, catheter and balloon can be used to position and expand the stent. Implantation of mono-tubular stents such as stent 100 is conventional and within the purview of a person skilled in the art. Further, mono-tubular stent 100 can be modified to provided

localized reinforcement at certain points by judicious use of bars and segments similar to reinforcing bar 75 and reinforcing segment 80, respectively, used to reinforce intersection point 40 of stent 10 (Figure 2).

Still further, the stent depicted in Figures 1-3 can be modified to omit, on a selected basis, first repeating pattern A and/or second repeating B with a view to improve flexibility of the stent and to allow access to other structures (e.g. side branches/arteries) outside the bounds of the stent.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications of the illustrative embodiments, as well as other embodiments of the invention , will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments.

What is claimed is:

1. An expandable bifurcated stent comprising a proximal end and a distal end in communication with one another, the proximal end comprising a primary passageway and the distal end comprising a pair of secondary passageways, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force exerted on the stent.

2. The bifurcated stent defined in claim 1, wherein the primary passageway is elongate and has a longitudinal axis which substantially bisects the pair of secondary passageways.

3. The bifurcated stent defined in claim 2, wherein the primary passageway is porous.

4. The bifurcated stent defined in claim 3, wherein the porosity of the primary passageway is defined by a plurality intersecting members.

5. The bifurcated stent defined in claim 4, wherein the intersecting members define a first repeating pattern.

6. The bifurcated stent defined in claim 5, wherein the first repeating pattern is a polygon having a pair of side walls substantially parallel to the longitudinal axis of the primary passageway, a first concave-shaped wall and a second convex-shaped wall connecting the side walls, the first wall and the second wall being equidistant along an axis which is parallel to the longitudinal axis of the primary passageway.

and thus, are best suited to be delivered and implanted in-line in th body passageway. These known stents are inappropriate for use in a bifurcated body passageway (e.g. a body passageway comprising a parent passageway that splits into a pair of passageways). Further, these stents are inappropriate for use in a body passageway having side branches since: (i) accurate placement of the stent substantially increases the risk to the patient, (ii) the risk of passageway closure in the side branches is increased, and (iii) the side branches will be substantially inaccessible.

Indeed the Physician Guide published in support of the Palmaz-Schatz stent states on page 32:

" ... no attempt should be made following placement of a PALMAZ-SCHATZ stent to access the side branch with a guide wire or a balloon, as such attempts may result in additional damage to the target vessel or the stent. Attempts to treat obstructed side branches within stented segments can result in balloon entrapment, necessitating emergency bypass surgery."

Thus, when installed, the Palmaz-Schatz stent admittedly shields side branches emanating from the target area of the body passageway effectively permanently. This can be problematic since the only way to treat blockage or other problems associated with the side branches is to perform the type of surgery which installation of the stent was intended to avoid.

This contraindication for conventional mono-tubular stents is corroborated by a number of investigators. See, for example, the following:

1. *Interventional Cardiovascular Medicine: Principles and Practice* (1994); Publisher: Churchill Livingstone Inc.; pages 221-223 (Ohman et al.), 487-488 (Labinaz et al.), 667-668 (Bashore et al.) and 897 (Bailey et al.), including references cited therein;

2. Gianturco-Roubin Flex-Stent™ Coronary Stent: Physician's Guide; page 2, Paragraph 3 under WARNINGS;

3. *Circulation*, Vol. 83, No. 1, January 1991 (Schatz et al.); entitled "Clinical Experience With the Palmaz-Schatz Coronary Stent"; pages 148-161 at page 149; and

4. *American Heart Journal*, Vol. 127, No. 2, February 1994 (Eeckhout et al.); entitled "Complications and follow-up after intracoronary stenting: Critical analysis of a 6-year single-center experience"; pages 262-272 at page 263.

Further, some investigators have attempted to install individual stents in each branch of the bifurcated body passageway. However, this approach is fraught with at least two significant problems. First, implantation of three individual stents, together with the expansive forces generated upon implantation results in subjecting the central walls of the bifurcated body passageway to undue stress which may lead to post-procedural complications. Second, since the central walls of the bifurcated body passageway are not supported by the individual stents, this area of the passageway is left substantially unprotected and susceptible to blockage.

One particular problem area with bifurcated body passageways is the occurrence of bifurcation lesions within the coronary circulation. Generally, these legions may be classified as follows:

Type	Characteristic
A	Prebranch stenosis not involving the ostium of the side branch;
B	Postbranch stenosis of the parent vessel not involving the origin of the side branch;
C	Stenosis encompassing the side branch but not involving the ostium;
D	Stenosis involving the parent vessel and ostium of the side branch;
E	Stenosis involving the ostium of the side branch only; and
F	Stenosis discretely involving the parent vessel and ostium of the side branch.

See *Atlas of Interventional Cardiology* (Popma et al.), 1994, pages 77-79. The presence of bifurcation lesions is predictive of increased procedural complications including acute vessel closure.

Detailed classification of other bifurcated body passageways is relatively undeveloped given the lack of non-surgical treatment approaches.

7. The bifurcated stent defined in claim 6, wherein the first wall and the second wall are substantially arcuate.

8. The bifurcated stent defined in any one of claims 5 or 6, wherein the intersecting members define a second repeating pattern.

9. The bifurcated stent defined in claim 8, wherein the second repeating pattern is a substantial mirror image of the first repeating pattern taken along an axis substantially normal to the longitudinal axis of the primary passageway.

10. The bifurcated stent defined in any one of claims 1-9, wherein the secondary passageway is elongate and has a longitudinal axis which intersects the longitudinal axis of the primary passageway at an acute angle.

11. The bifurcated stent defined in claim 10, wherein the secondary passageway is porous.

12. The bifurcated stent defined in claim 11, wherein the porosity of each secondary passageway is defined by a plurality intersecting members.

13. The bifurcated stent defined in claim 12, wherein the intersecting members define a first repeating pattern.

14. The bifurcated stent defined in claim 13, wherein the first repeating pattern is a polygon having a pair of side walls substantially parallel to the longitudinal axis of the secondary passageway, a first concave-shaped wall and a second convex-shaped wall connecting the

side walls, the first wall and the second wall being equidistant along an axis which is parallel to the longitudinal axis of the secondary passageway.

15. The bifurcated stent defined in claim 14, wherein the first wall and the second wall are substantially arcuate.

16. The bifurcated stent defined in any one of claims 13 or 14, wherein the intersecting members define a second repeating pattern.

17. The bifurcated stent defined in claim 16, wherein the second repeating pattern is a substantial mirror image of the first repeating pattern taken along a line substantially normal to the longitudinal axis of the secondary passageway.

18. The bifurcated stent defined in claim 1, wherein the primary passageway is connected to the each of the secondary passageways at an intersection point.

19. The bifurcated stent defined in claim 18, wherein the intersection point reinforced with respect to the remainder of the stent.

20. The bifurcated stent defined in any one of claims 18 or 19, wherein the intersection point is porous.

21. The bifurcated stent defined in claim 20, wherein the porosity of the intersection point is defined by a plurality intersecting members.

22. The bifurcated stent defined in claim 21, wherein the intersecting members define a third repeating pattern.

23. The bifurcated stent defined in claim 22, wherein the third repeating pattern is a polygon having a pair of side walls substantially parallel to the longitudinal axis of the primary passageway, a first concave-shaped wall and a second convex-shaped wall connecting the side walls, the first wall and the second wall being equidistant along an axis which is parallel to the longitudinal axis of the primary passageway, and a reinforcing bar disposed between and substantially parallel to the pair of side walls.

24. The bifurcated stent defined in claim 23, wherein the reinforcing bar is disposed substantially equidistant from each of the side walls.

25. The bifurcated stent defined in claim 1, wherein the primary passageway has a substantially circular cross-section.

26. The bifurcated stent defined in claim 1, wherein each of the secondary passageways has a substantially circular cross-section.

27. The bifurcated stent defined in claim 1, wherein the cross-sectional area of the primary passageway is substantially the same as the sum of the cross-sectional areas of each secondary passageway.

28. The bifurcated stent defined in claim 1, wherein the distal end is flexible with respect to the remainder of the stent.

29. The bifurcated stent defined in claim 1, wherein the proximal end is flexible with respect to the remainder of the stent.

30. The bifurcated stent defined in claim 1, wherein the length of each of the primary passageway and the second passageways is substantially the same.

31. An expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality intersecting members arranged to define a first repeating pattern which is a polygon having a pair of side walls substantially parallel to the longitudinal axis, a first concave-shaped wall and a second convex-shaped wall connecting the side walls, the first wall and the second wall being equidistant along an axis which is parallel to the longitudinal axis, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent.

32. The stent defined in claim 33, wherein the first wall and the second wall are substantially arcuate.

33. The stent defined in claim 31, wherein the intersecting members define a second repeating pattern.

34. The stent defined in claim 33, wherein the second repeating pattern is a substantial mirror image of the first repeating pattern taken along a line substantially normal to the longitudinal axis.

35. A method for delivery to a target body passageway of an expandable bifurcated stent comprising a proximal end and a distal end in communication with one another, the proximal end comprising a primary passageway and the distal end comprising a pair of secondary passageways, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force from the interior of the stent, the method comprising the steps of:

disposing the stent in the first, contracted position on a catheter;

inserting the stent and catheter within the target body passageway by catheterization of the target body passageway;

exerting a radially outward expansive force on the stent such that the stent assumes the second, expanded position and is urged against the target body passageway.

36. The method defined in claim 35, wherein the expansive force is provided by expanding the catheter such that the stent assumes the second, expanded position and is urged against the target body passageway.

37. The method defined in claim 36, comprising the further steps of:

collapsing the catheter; and

removing the catheter from the target body passageway.

38. The method defined in any one of claims 34-37, wherein the expansive force is provided simultaneously to the primary passageway and each of the secondary passageways.

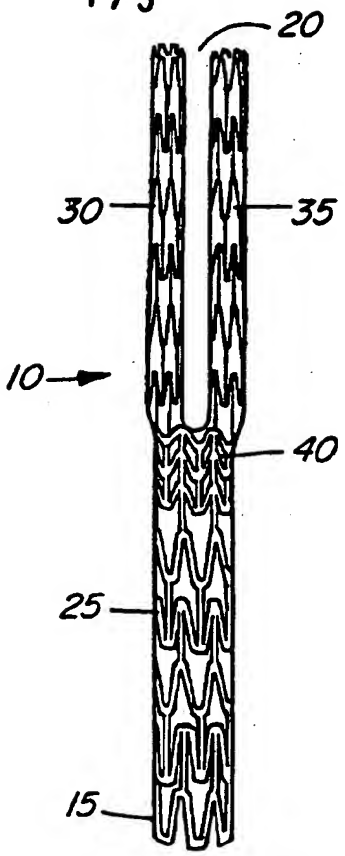

FIG. 1

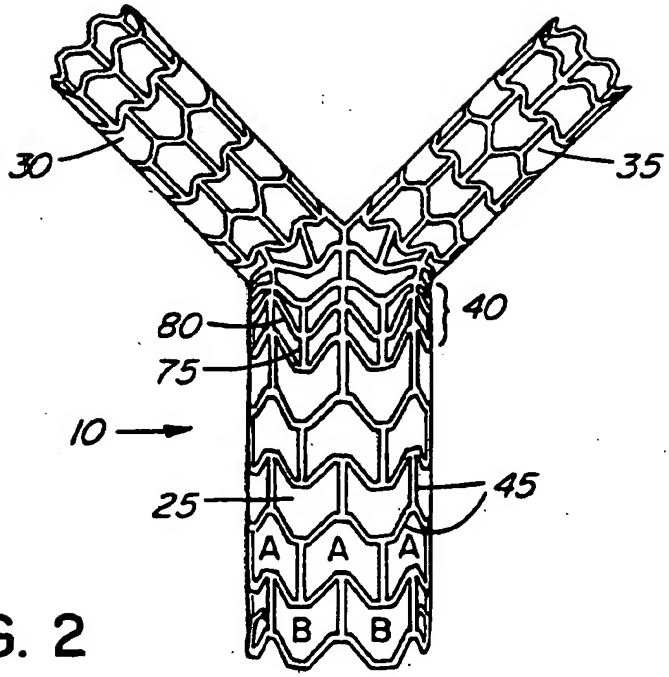

FIG. 2

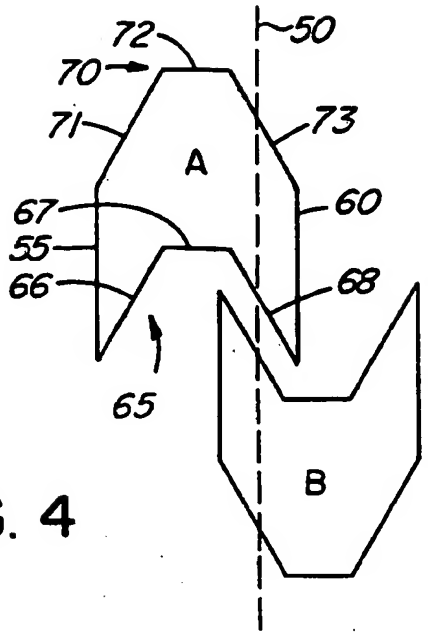

FIG. 4

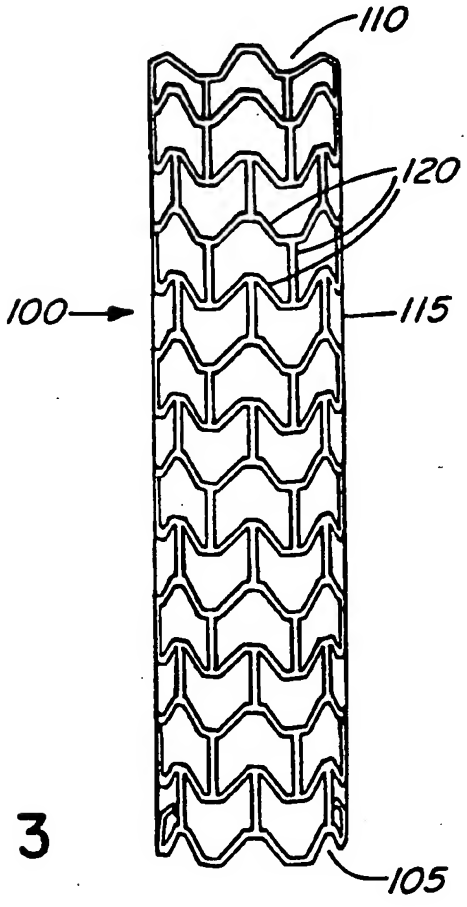

FIG. 3

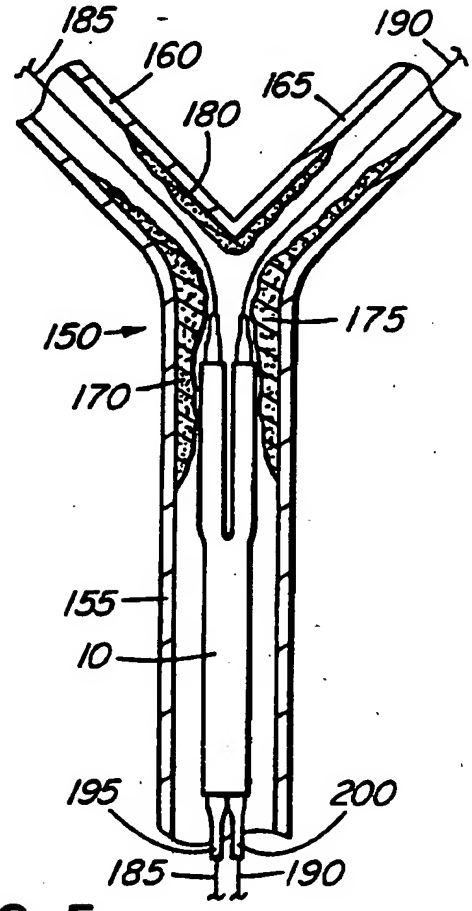

FIG. 5

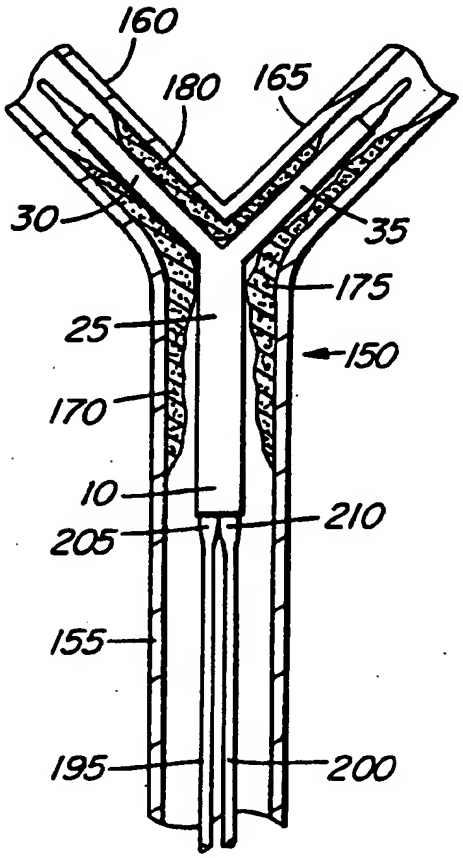

FIG. 6

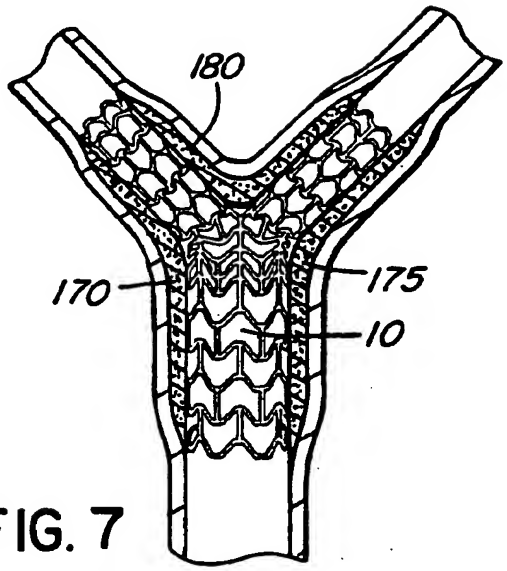

FIG. 7

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/CA 95/00628

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,4 994 071 (D. C. MACGREGOR) 19 February 1991	1-5, 10-13, 18,20, 21,25-30
Y	see abstract	6-9, 14-17

X	WO,A,94 12136 (BOSTON SCIENTIFIC CORPORATION) 9 June 1994	31-34
Y	see abstract; figure 6	6-9, 14-17

A	FR,A,2 678 508 (CELSA LG) 8 January 1993 see figure 3	19

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
8 March 1996	14.03.96
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Authorized officer Wolf, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/CA 95/00628

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO,A,95 26695 (PROGRAFT MEDICAL, INC.) 12 October 1995	31-34
P,A	see page 40, line 3 - line 12; figure 23	1-9, 11-17

P,X	WO,A,95 09584 (GUERBET S.A.) 13 April 1995	31,33
P,A	see figure 4	6,8

1

It would be desirable to have an expandable stent which obviates or mitigates the above-mentioned disadvantages of the prior art.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a novel expandable stent which obviates or mitigates at least one of the above-mentioned disadvantages of the prior art.

Accordingly, the present invention provides an expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of intersecting members integrally connected to one another at their points of intersection, the plurality of intersecting members defining a first repeating pattern which, in two dimensions and the unexpanded state of the stent, is a polygon having a pair of side walls substantially parallel to the longitudinal axis, a first concave-shaped wall and a second convex-shaped wall connecting the side walls, the stent comprising at least two circumferentially disposed rings of first repeating pattern, the stent being expandable from a first, contracted position in which the tubular wall is not folded along the longitudinal axis to a second, expanded position upon the application of a radially outward force on the stent, characterised in that both of the first concave-shaped wall and the second convex-shaped wall have a flat apex in the form of a segment which is normal to the longitudinal axis.

The Applicant's have also discovered that the use of a specific repeating pattern in a porous stent is particularly advantageous. Generally, the repeating pattern is a polygon having a pair of side walls substantially parallel to the longitudinal axis of the stent passageway in question, a first concave-shaped wall and a second convex-shaped wall connecting the side walls, the first wall and the second wall being equidistant along an axis which is parallel to the longitudinal axis of the stent passageway in question. As used throughout this specification, the terms "concave-shaped" and "convex-shaped" are intended to have a broad meaning and a shape having apex. The important point is that the apex of the concave-shaped wall is directed into the polygon whereas the apex of the convex-shaped wall is directed away from the polygon.

A preferred aspect of the present invention relates to the provision of an expandable bifurcated stent comprising the specific repeating pattern. To the knowledge of the Applicant's, such an expandable bifurcated stent has heretofore been unknown. As used throughout this specification, the term "biffurcated stent" is intended to have a broad meaning and encompasses any stent having a primary passageway to which is connected at least two secondary passageways. Thus, trifurcated stents are encompassed herein. Further, one of the secondary passageways can he a continuation of the primary passageway with the result that the other secondary passageway is essentially a side branch to the primary passageway.

Thus, this repeating pattern is useful in both the novel bifurcated stent described herein and conventional mono-tubular stents. The advantages associated with the use of such a repeating pattern include the following:

1. The stent is controllably expandable;
2. The stent is flexible and thus, can be deliver via and/or implanted in curved body passageways; and
3. Access to side branches is maintained, unlike the Palmaz-Schatz stent described hereinabove.

The stent of the present invention (bifurcated or mono-tubular) can further comprise coating material therein. The coating material can be one or more of a biologically inert material (i.e. to reduce the thrombogenicity of the stent), a medicinal composition which leaches in the wall of the body passageway after implantation (e.g. to provide anticoagulant action and the like).

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will be described with reference to the accompanying drawings wherein like numerals designate like parts and in which:

Figure 1 illustrates a perspective view of a bifurcated stent in a first, contracted position;
Figure 2 illustrates an enlarged perspective view of the bifurcated stent of Figure 1 in a second, expanded position;
Figure 3 illustrates a perspective view of a mono-tubular stent in a second, expanded position;
Figure 4 illustrates an expanded two-dimensional representation of the repeating patterns present in the stents illustrated in Figure 1-3;
Figure 5 illustrates a cross-section of a bifurcated body passageway into which the bifurcated stent of Figure 1 is being delivered;
Figure 6 illustrates a cross-section of a bifurcated body passageway in which the bifurcated stent of Figure 1 is positioned in a first, contracted position; and

INTERNATI NAL SEARCH REPORT

.national application No.
PCT/CA95/00628

Box I bservations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 35-38
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1(iv) Method for treatment of the human body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/CA 95/00628

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4994071	19-02-91	NONE		
WO-A-9412136	09-06-94	EP-A-	0664689	02-08-95
FR-A-2678508	08-01-93	NONE		
WO-A-9526695	12-10-95	AU-B-	2379595	23-10-95
		CA-A-	2157575	12-10-95
WO-A-9509584	13-04-95	FR-A-	2710834	14-04-95
		AU-B-	7858594	01-05-95

Figure 7 illustrates a cross-section of a bifurcated body passageway in which the bifurcated stent of Figure 1 positioned in a second, expanded position.

BEST MODE FOR CARRYING OUT THE INVENTION

With reference to Figure 1, there is illustrated a stent 10. Stent 10 comprises a proximal nd 15 and a distal end 20. Proximal end 15 comprises a primary passageway 25. Distal end 20 comprises a pair of secondary passageways 30,35 . Secondary passageways 30,35 are connected to primary passageway 25 at an intersection point 40. As will be appreciated by those of skill in the art, the length of primary passageway 25 and secondary passageways 30,35 is particularly restricted and is select to optimize both deliverability of the stent (shorten) and vessel coverage (lengthen).

With reference to Figure 2, there is illustrated an enlarged perspective view of the bifurcated stent illustrated in Figure 1 in a second, expanded position. As illustrated, secondary passageways 30,35 are split apart more than they are when the bifurcated stent is in the first, contracted position (Figure 1).

As illustrated, primary passageway 25 and secondary passageways 30,35 are porous. The porosity of these passageways is defined by a plurality of intersecting members 45. Intersecting members 45 define a first repeating pattern designated A and a second repeating pattern designated B in Figure 2. The nature of first repeating pattern A and second repeating pattern B will be discussed in more detail hereinbelow with reference to Figure 4.

With reference to Figure 3, there is illustrated a perspective view of a mono-tubular stent 100. Stent 100 comprises a proximal end 105 and a distal end 110. Disposed between proximal end 105 and distal end 110 is a tubular wall 115. Tubular wall 115 is porous. The porosity of tubular wall 115 is defined by a plurality of intersecting members 120 which define a first repeating pattern A and second repeating pattern B.

With reference to Figure 4, there is illustrated an enlarged two-dimensional representation of first repeating pattern A and second repeating pattern B. These repeating patterns are illustrated with respect to a longitudinal axis 50 which is representative of the longitudinal axis which would be present in each of primary passageway 25, secondary passageways 30,35 and tubular wall 115 discussed above with reference to Figures 1, 2 and 3. As illustrated, repeating pattern A is a polygon comprising a pair of side walls 55,60. Side walls 55,60 are substantially parallel to longitudinal axis 50. Side walls 55,60 are connected by a concave-shaped wall 65 and a convex-shaped wall 70.

As illustrated, concave-shaped wall 65 is made up of a trio of segments 66,67,68. In the illustrated embodiment, segment 67 is the apex of concave-shaped wall 65. Convex-shaped wall 70 is made up of a trio of segments 71,72,73. In the illustrated embodiment, segment 72 is the apex of convex-shaped wall 70.

It will be appreciated by those of skill in the art that the provision of first repeating pattern A, as illustrated, necessarily defines and provides for second repeating pattern B. It will also be appreciated by those of skill in the art that second repeating pattern B is a mirror image of first repeating pattern A taken along an axis (not shown) substantially normal to longitude general axis 50.

It will be further appreciated by those of skill in the art that the shape of concave-shaped wall 65 and/or convex-shaped wall 70 can be modified without departing from the scope of the appended claims For example, more than three segments can be used to define concave-shaped wall 65 and/or convex-shaped wall 70.

It is furthermore possible to omit one or both of side walls 55,60 at selected points along the body of the stent with a view to improving the longitudinal flexibility of the stent. Further, it is possible to omit one or more of segments 71,72,73 at selected points along the body of the stent with a view to improving the lateral flexibility of the stent.

With further reference to Figure 2, it will be evident to those of skill in the art that intersection point 40 is an annular arrangement of second repeating pattern B which has been modified. Specifically, the modification is in two areas. First, a reinforcing bar 75 has been disposed between side walls 55,60 to connect segments 67 and 72. Second, a reinforcing segment 80 is provided midway between and has a similar shape to concave-shaped wall 65 and convex-shaped wall 70. These two areas of modification serve to reinforce intersection point 40. This facilitates alleviation of stresses under which this area of stent 10 is placed when it is expanded. It will of course be appreciated by those of skill in the art that modifications can be made to the design of intersection point 40. For example, the flexibility of stent 10 at intersection point 40 can be modified by judicious addition or omission of further reinforcing bars 75 and/or reinforcing segments 80.

With reference to Figures 5 and 6, there is illustrated a bifurcated body passageway 150 comprised of a proximal passageway 155 and a pair of distal passageways 160,165. As illustrated, bifurcated body passageway 150 comprises a Type "D" Bifurcation lesion having characteristic blockages 170,175,180.

Stent 10 is delivered to bifurcated body passageway 150 in the following manner. Initially, a pair of guidewires 185,190 are inserted into proximal passageway 155 such that guidewire 185 enters distal passageway 160 and guidewire 190 enters distal passageway 165. The manner by which the guidewires are inserted is conventional and within the purview of a person skilled in the art.

As illustrated, stent 10 is positioned in association with a pair of catheters 195,200 (for clarity, the interior of stent 10 is not shown). Catheter 195 has associated with it a balloon 205. Catheter 200 has associated with it a balloon 210. Balloons 205,210 substantially fill primary passageway 25 of stent 10. Balloon 205 substantially fills secondary pas-

sageway 30 of stent 10. Balloon 210 substantially fills secondary passageway 35 of stent 10.

The stent/catheter/balloon combination is delivered through proximal passageway 155 with the aid of guidewires 185,190. As the stent/catheter/balloon combination approaches distal passageways 160,165, predisposition of guidewires 185,190 serves to separate secondary passageways 30,35 to be disposed in distal passageways 160,165, respectively. Thus, as illustrated in Figure 6, stent 10 is positioned in place.

Once stent 10 is in position, balloons 205,210 are expanded resulting in implantation of stent 10 in the corresponding interior surfaces of proximal passageway 155 and distal passageways 160,165. Upon implantation of stent 10, balloons 205,210 are collapsed. Thereafter, catheters 195,200 and guidewires 185,190 have been removed leaving the implanted stent 10 shown in Figure 7. As illustrated in Figure 7, blockages 170,175,180 are bulged radially outwardly in combination with the appropriate portions of proximal passageway 155 and distal passageways 160,165 resulting in a reduction in the overall blockage in bifurcated body passage 150.

It will be apparent to those of skill in the art that implantation of stent 10 can be accomplished by various other means. For example, it is contemplated that it is possible to substitute the pair of catheter/balloon combinations illustrated in Figures 5 and 6 with a single, bifurcated catheter/balloon design which mimics the design of the stent. Thus, in this modification, the balloon and guidewire would be design to mimic the bifuracted design of the stent. As further alternative, it is contemplated that the stent can be made of a suitable material which will expand when bifurcated body passageway 150 is flushed with a liquid having an elevated temperature (e.g. 65,6°C-71,1°C (150°F-160°F)). Further, stent 10 can be designed to expand upon the application of mechanical forces other than those applied by a balloon/catheter. Still further, stent 10 can be designed self-expanding to be implanted as described above. In this embodiment, the radially outward force exerted on the stent would be generated within the stent itself.

With regard to mono-tubular stent 100 depicted in Figure 3, this stent can be implanted using a system similar to the one described above with reference to bifurcated stent 10 (Figures 5-7). In this instance, of course, a single guidewire, catheter and balloon can be used to position and expand the stent. Implantation of mono-tubular stents such as stent 100 is conventional and within the purview of a person skilled in the art. Further, mono-tubular stent 100 can be modified to provided localized reinforcement at certain points by judicious use of bars and segments similar to reinforcing bar 75 and reinforcing segment 80, respectively, used to reinforce intersection point 40 of stent 10 (Figure 2).

Still further, the stent depicted in Figures 1-3 can be modified to omit, on a selected basis, first repeating pattern A and/or second repeating B with a view to improve flexibility of the stent and to allow access to other structures (e.g. side branches/arteries) outside the bounds of the stent.

Claims

1. An exandable stent (10,100) comprising a proximal end (15,105) and a distal end (20,110) in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis (50) and a porous surface defined by a plurality of intersecting members (45,120) integrally connected to one another at their points of intersection, the plurality of intersecting members defining a first repeating pattern (A) which, in two dimensions and the unexpanded state of the stent, is a polygon having a pair of side walls (55,60) substantially parallel to the longitudinal axis, a first concave-shaped wall (65) and a second convex-shaped wall (70) connecting the side walls, the stent comprising at least two circumferentially disposed rings of first repeating pattern (A), the stent being expandable from a first, contracted position in which the tubular wall is not folded along the longitudinal axis to a second, expanded position upon the application of a radially outward force on the stent, characterised in that both of the first concave-shaped wall (65) and the second convex-shaped wall (70) have a flat apex in the form of a segment (67,72) which is normal to the longitudinal axis.

2. The stent defined in claim 1, wherein the intersecting members define a second repeating pattern (B).

3. The stent defined in claim 2, wherein the second repeating pattern is a substantial minor image of the first repeating pattern taken along a line substantially normal to the longitudinal axis.

4. The stent defined in any one of claims 1-3, wherein the first wall and the second wall are substantially arcuate.

5. The stent defined in any one of claims 1-4, wherein the first concave-shaped wall comprises three segments.

6. The stent defined in any one of claims 1-4, wherein the second convex-shaped wall comprises three segments.

7. The stent defined in any one of claims 1-4, wherein each of the first concave-shaped wall and the second convex-shaped wall comprise three segments.

8. The stent defined in any one of claims 1-7, further comprising a coating material thereon.

9. The stent defined in claim 8, wherein the coating material is selected from the group comprising biologically inert material, a medicinal composition and mixtures thereof.

Patentansprüche

1. Aufweitbarer Stent (10, 100) mit einem proximalen Ende (15, 105) und einem distalen Ende (20, 110), die miteinander in Verbindung stehen, mit einer hülsenförmigen Wand, die zwischen dem proximalen und dem distalen Ende angeordnet ist und eine Längsachse (50) aufweist sowie eine poröse Fläche, gebildet aus einer Mehrzahl von sich schneidenden Elementen (45, 120), die an ihren Schnittstellen integral miteinander verbunden sind und die ein erstes, sich wiederholendes Muster (A) bilden, das in zwei Dimensionen und bei nicht expandiertem Zustand des Stent ein Polygon mit einem Paar Seitenwänden (55, 60) ist, die im wesentlichen parallel zur Längsachse verlaufen, mit einer ersten konkaven Wand (65) und einer zweiten konvexen Wand (70), die die Seitenwände miteinander verbinden, ferner mit wenigstens zwei in Umfangsrichtung angeordneten Ringen des ersten sich wiederholenden Musters (A), so daß der Stent expandierbar ist zwischen einer ersten, kontrahierten Position, in welcher die hülsenförmige Wand entlang der Längsachse nicht gefaltet ist, und einer zweiten, expandierten Position nach dem Aufbringen einer radial auswärtigen Kraft auf den Stent, dadurch gekennzeichnet, daß die erste konkave Wand (65) und die zweite konvexe Wand (70) einen flachen Scheitel in Gestalt eines Segmentes (67, 72) aufweisen, das zur Längsachse senkrecht verläuft.

2. Stent nach Anspruch 1, dadurch gekennzeichnet, daß die sich schneidenden Elemente ein zweites, sich wiederholendes Muster (B) bilden.

3. Stent nach Anspruch 2, dadurch gekennzeichnet, daß das zweite sich wiederholende Muster im wesentlichen ein Spiegelbild des ersten sich wiederholenden Musters entlang einer zur Längsachse im wesentlichen senkrechten Linie gesehen ist.

4. Stent nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die erste und die zweite Wand im wesentlichen bogenförmig sind.

5. Stent nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die erste konkave Wand drei Segmente umfaßt.

6. Stent nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die zweite konvexe Wand drei Segmente umfaßt.

7. Stent nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die erste konkave und die zweite konvexe Wand jeweils drei Segmente umfassen.

8. Stent nach einem der Ansprüche 1 bis 7, weiterhin umfassend eine hierauf befindliche Beschichtung.

9. Stent nach Anspruch 8, dadurch gekennzeichnet, daß das Beschichtungsmaterial ausgewählt ist aus der Gruppe, umfassend ein biologisch inertes Material, eine medizinische Verbindung sowie Gemische hiervon.

Revendications

1. Une prothèse endovasculaire extensible (10, 100) comprenant une extrémité proximale (5,105) et une extrémité distale (20,110) communiquant l'une avec l'autre, une paroi tubulaire disposée entre l'extrémité proximale et l'extrémité distale, la paroi tubulaire ayant un axe longitudinal (50) et une surface poreuse définie par une pluralité d'éléments se croisant (45,120) reliés solidairement les uns aux autres à leurs points d'intersection, la pluralité d'éléments se croisant définissant un premier réseau répétitif (A) qui, en deux dimensions et à l'état non dilaté de la prothèse endovasculaire, est un polygone ayant une paire de parois latérales (55, 60) sensiblement parallèles à l'axe longitudinal, une première paroi de forme concave (65) et une seconde paroi de forme concave (70) reliant les parois latérales, la prothèse endovasculaire comprenant au moins deux anneaux disposés circonférentiellement du premier réseau répétitif (A). la prothèse endovasculaire étant extensible à partir d'une première, position contractée dans laquelle la paroi tubulaire n'est pas repliée le long de l'axe longitudinal, jusqu'à une seconde, position dilatée après application d'une force radiale dirigée vers l'extérieur sur la prothèse endovasculaire, caractéri-

sée en ce que à la fois la première paroi de forme concave (65) et la seconde paroi de forme convexe (70) ont un apex plat sous la forme d'un segment (67, 72), qui est normal à l'axe longitudinal

2. La prothèse endovasculaire selon la revendication 1, dans lequel les éléments se croisant définissent un second réseau répétitif (B).

3. La prothèse endovasculaire selon la revendication 2, dans lequel le second réseau répétitif est une image sensiblement spéculaire du premier réseau répétitif pris le long d'une ligne sensiblement normale à l'axe longitudinal.

4. La prothèse endovasculaire selon l'une quelconque des revendications 1 à 3, dans lequel la première paroi et la seconde paroi sont sensiblement arquées.

5. La prothèse endovasculaire selon l'une quelconque des revendications 1 à 4, dans lequel la première paroi de forme concave comprend trois segments.

6. La prothèse endovasculaire selon l'une quelconque des revendications 1 à 4, dans lequel la seconde paroi de forme convexe comprend trois segments.

7. La prothèse endovasculaire selon l'une quelconque des revendications 1 à 4, dans lequel chacune parmi la première paroi de forme concave et la seconde paroi de forme convexe comprend trois segments.

8. La prothèse endovasculaire selon l'une quelconque des revendications 1 à 7, comprenant en outre un matériau de revêtement appliqué dessus.

9. La prothèse endovasculaire selon la revendication 8, dans lequel le matériau de revêtement est choisi dans le groupe comprenant du matériau biologiquement inerte, une composition médicinale et leurs mélanges.

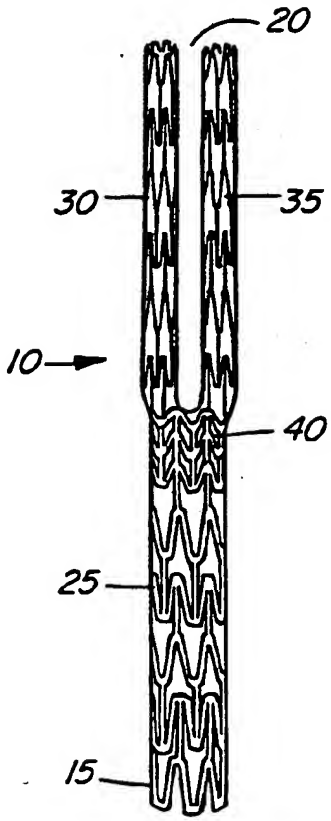

FIG. 1

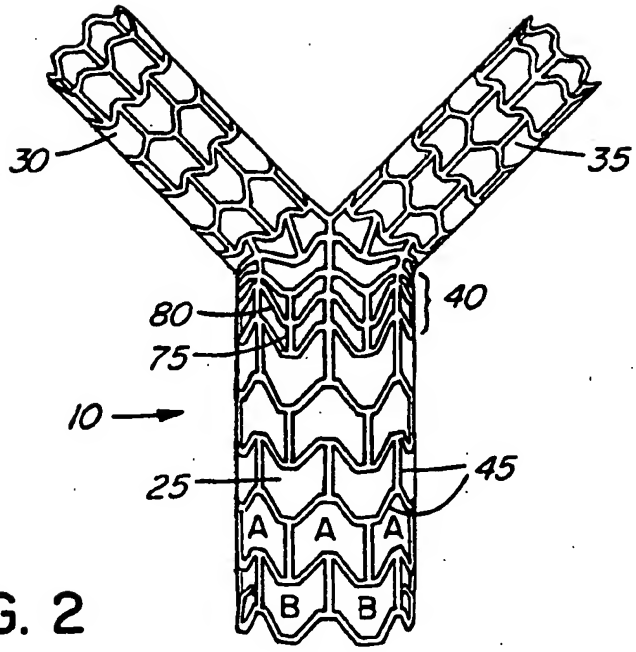

FIG. 2